

## **PSJ2 Exh 121**

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# Audit Committee Meeting

November 1, 2012

1:00 – 4:00 PM Eastern Time



**CardinalHealth**

**CONFIDENTIAL**



**CARDINAL HEALTH CONFIDENTIAL**

To: Audit Committee Members of the Board of Directors:  
Glenn A. Britt, Chair, Carrie S. Cox, Bruce L. Downey, John F. Finn,  
David P. King, Clayton M. Jones

From: Jeff Miller  
General Auditor

Cc: George S. Barrett, Jeffrey W. Henderson, John M. Adams, Jr., Craig S.  
Morford, Stephen T. Falk, Stuart G. Laws, Jonathan G. Weaver (E&Y)

Date: October 26, 2012

Subject: Audit Committee Meeting Pre-Meeting Materials

Enclosed are the agenda and materials for the November 1, 2012 Audit Committee meeting. As is our general practice, all presenters are planning to focus on highlights of their materials and will, therefore, rely on your pre-meeting review to direct discussion to other areas of interest.

In the interest of time, a number of agenda items have been designated as "pre-read only" (marked with an \*). These items will only be discussed at the meeting if you have questions.

The meeting is scheduled for 1:00-4:00 p.m. EST.

Please feel free to contact me at (614) 757-7731 if you have questions.





**AGENDA  
CARDINAL HEALTH, INC.  
AUDIT COMMITTEE MEETING**

**November 1, 2012  
1:00 – 4:00 p.m. Eastern Time**

<b><u>Time+</u></b>		<b><u>Topic</u></b>	<b><u>Action</u></b>	<b><u>Presenter</u></b>
1:00	1.	Approve Minutes of the August 7, 2012, August 20, 2012 and October 26, 2012 Audit Committee Meetings	Y	Glenn Britt
1:00	2.	Financial Results <ul style="list-style-type: none"> <li>• Review of Draft Form 10Q, including Management Discussion and Analysis</li> </ul>		Jeff Henderson Stu Laws
1:25	3.	Chief Accounting Officer Update <ul style="list-style-type: none"> <li>• SAB 108 Assessment*</li> <li>• Summary of Restructuring Projects*</li> <li>• Balance Sheet Analytical*</li> <li>• Reserve Summary*</li> <li>• Adequacy and Effectiveness of Disclosure Controls*</li> <li>• Pre-approved Independent Auditor Fees*</li> </ul>		Stu Laws
1:35	4.	Ernst & Young LLP <ul style="list-style-type: none"> <li>• Q1 FY13 Review Results and Required Communications               <ul style="list-style-type: none"> <li>○ Update of Required Communications</li> </ul> </li> <li>• FY13 Cardinal Health Integrated Audit Plan               <ul style="list-style-type: none"> <li>○ Financial Statement Audit Plan and Timeline</li> <li>○ Client Service Team</li> </ul> </li> <li>• Coordinating Partner Rotation Process and Timing</li> <li>• Other Topics</li> </ul>		Jon Weaver Mary Betsill Andrea Hecht
1:50	5.	CFO Overview <ul style="list-style-type: none"> <li>• Follow-Ups from Prior Audit Reports</li> <li>• Financial Benefits Plan Committee Update*</li> </ul>		Jeff Henderson
2:00	6.	Tax Update <ul style="list-style-type: none"> <li>• Tax Transformation Update</li> <li>• Controversy Overview</li> </ul>		Sam Samad Mark Stauffer
2:15	7.	Global Assurance Services Update <ul style="list-style-type: none"> <li>• SOX 404 FY13 Status</li> <li>• Corporate Audit Update</li> </ul>		Jeff Miller

2:30	8.	Chief Information Officer Update	Patty Morrison
		<ul style="list-style-type: none"> <li>• IT Security and Controls Update</li> <li>• Follow-Ups from Prior Audit Reports</li> <li>• IT Security Awareness Program</li> <li>• MBT Update</li> </ul>	
2:45	9.	Chief Legal and Compliance Officer Update	Craig Morford
		<ul style="list-style-type: none"> <li>• Quality and Regulatory Update</li> <li>• Ethics and Compliance Program Update</li> </ul>	
3:00	10.	General Counsel Update	Steve Falk
		<ul style="list-style-type: none"> <li>• Litigation Update</li> <li>• Other Matters</li> </ul>	
3:15	11.	Audit Committee Matters	Glenn Britt
		<ul style="list-style-type: none"> <li>• Review/Update Audit Committee Charter</li> <li>• Audit Committee Calendar*</li> </ul>	Y

### **EXECUTIVE SESSIONS**

3:25	12.	Audit Committee Sessions Alone	
		<ul style="list-style-type: none"> <li>• CEO and CFO               <ul style="list-style-type: none"> <li>○ Approval of EY Engagement Letter</li> <li>○ Audit Partner Rotation Discussion</li> </ul> </li> <li>• CFO</li> <li>• Chief Legal and Compliance Officer and General Counsel               <ul style="list-style-type: none"> <li>○ Business Conduct Line Reports</li> </ul> </li> <li>• Ernst &amp; Young LLP</li> <li>• General Auditor</li> <li>• Executive Session Only</li> </ul>	Y
4:00		Adjourn	Glenn Britt

#### **Attendees:**

##### **Committee Members**

Glenn A. Britt  
 Carrie S. Cox  
 Bruce L. Downey  
 John F. Finn  
 David P. King

##### **Other Attendees**

George S. Barrett  
 John M. Adams, Jr.  
 Stephen T. Falk  
 Jeffrey W. Henderson  
 Stuart G. Laws  
 Jeffrey S. Miller

Craig S. Morford  
 Patricia B. Morrison  
 Sam Samad  
 Mark F. Stauffer  
 Mary K. Betsill – EY  
 Andrea K. Hecht - EY  
 Jonathan G. Weaver – EY  
 Clayton M. Jones

\*Pre-Read only

+Anticipated start times; to be adjusted as discussion warrants

ITEM 1  
APPROVAL OF MEETING MINUTES

## MATERIALS TO BE PROVIDED IN SUPPLEMENTAL MAILING

- October 26, 2012 meeting minutes

**CARDINAL HEALTH, INC.  
MINUTES OF MEETING OF AUDIT COMMITTEE**

**August 7, 2012**

A regular quarterly meeting of the Audit Committee (the "Committee") of the Board of Directors of Cardinal Health, Inc. (the "Company") was held on August 7, 2012 at 1:00 p.m. Eastern time at the Company's offices in Dublin, Ohio pursuant to a call to order by the Chairman of the Committee and notice duly given to all members of the Committee.

The meeting was attended by Committee Chairman Glenn A. Britt and Committee members Carrie S. Cox, Bruce L. Downey, John F. Finn and David P. King. Also attending at the invitation of the Committee were Chairman and Chief Executive Officer George S. Barrett, Chief Financial Officer Jeffrey W. Henderson, Chief Legal and Compliance Officer Craig S. Morford, Executive Vice President, General Counsel and Corporate Secretary Stephen T. Falk, Senior Vice President and Chief Accounting Officer Stuart G. Laws, Senior Vice President and Chief Financial Officer- Pharmaceutical Segment Jorge Gomez, Senior Vice President and Treasurer Sam Samad, Vice President and General Auditor Jeffrey S. Miller and Senior Vice President, Associate General Counsel and Assistant Secretary John M. Adams, Jr., who served as secretary of the meeting. Also present at the meeting at the invitation of the Committee were Ernst & Young LLP ("E&Y") partner Jonathan G. Weaver and senior manager Andrea K. Hecht. Chairman Britt participated by telephone.

Mr. Britt called the meeting to order at 1:00 p.m. The Committee approved the minutes of the meetings held on May 1, 2012 and July 31, 2012, drafts of which were provided with the materials distributed to the members of the Committee in advance of the meeting (the "Committee Pre-read Materials").

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Mr. Morford noted that he would present his year-end Annual Ethics and Compliance report to the full Board the next day, during which he would review the Company's controlled substance regulatory responsibilities and compliance program. As a result, he had not included a separate quarterly report for the Committee.

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## **Redacted - Not Responsive**

Mr. Falk discussed recent developments described in his report on significant litigation included in the Committee Pre-read Materials, including the State of West Virginia lawsuit and the inquiry by the Maryland Assistant United States Attorney regarding controlled substance distributions. Messrs. Morford and Falk responded to questions from Committee members.

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During their private session, Mr. Morford reviewed, among other things, business conduct line reports. The Committee members then met alone in executive session.

The meeting was adjourned at 3:55 p.m. Eastern time.

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John M. Adams, Jr.,  
Secretary of the Meeting

Privileged and Confidential  
Draft Dated 8/20/2012

**CARDINAL HEALTH, INC.  
MINUTES OF MEETING OF AUDIT COMMITTEE**

**August 20, 2012**

A meeting of the Audit Committee (the "Committee") of the Board of Directors of Cardinal Health, Inc. (the "Company") was held telephonically on August 20, 2012 at 1:00 p.m. Eastern time pursuant to call to order by the Chairman of the Committee and notice duly given to all members of the Committee.

The meeting was attended by Committee Chairman Glenn A. Britt and Committee members Carrie S. Cox, Bruce L. Downey and David P. King. Committee member John F. Finn was absent. Also attending at the invitation of the Committee were Director Calvin Darden, Chairman and Chief Executive Officer George S. Barrett, Chief Financial Officer Jeffrey W. Henderson, Chief Legal and Compliance Officer Craig S. Morford, Executive Vice President, General Counsel and Corporate Secretary Stephen T. Falk, Senior Vice President and Chief Accounting Officer Stuart G. Laws, Vice President and General Auditor Jeffrey S. Miller and Senior Vice President, Associate General Counsel and Assistant Secretary John M. Adams, Jr., who served as secretary of the meeting. Also present at the meeting at the invitation of the Committee were Ernst & Young LLP ("E&Y") partner Jonathan G. Weaver and senior manager Andrea K. Hecht.

Mr. Britt called the meeting to order at 1:00 p.m.

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The meeting was adjourned at 1:30 p.m. Eastern time.

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John M. Adams, Jr., Secretary of the Meeting

## ITEM 2

### FINANCIAL RESULTS

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## **Lakeland, Florida Distribution Center DEA Investigation and Related Matters**

On February 3, 2012 the United States Drug Enforcement Administration (the "DEA") issued an order to show cause and immediate suspension of our Lakeland, Florida distribution center's registration to distribute controlled substances, asserting that we failed to maintain required controls against the diversion of controlled substances. On May 14, 2012, we entered into a settlement agreement with the DEA under which our Lakeland registration will remain suspended until May 15, 2014 and the DEA confirmed that it was planning no further administrative actions at any of our other facilities based on conduct prior to the settlement. The settlement agreement did not foreclose the possibility of the U.S. Department of Justice (the "DOJ") seeking civil fines for conduct covered by the settlement agreement. In that regard, we are responding to civil subpoenas from two local offices within the DEA and the DOJ.

## **State of West Virginia vs. Cardinal Health, Inc.**

On June 26, 2012, the West Virginia Attorney General filed complaints against fourteen pharmaceutical wholesale distributors, including us, in the Circuit Court of Boone County, West Virginia alleging, among other things, that the distributors failed to maintain effective controls to guard against diversion of controlled substances in West Virginia, failed to report suspicious orders of controlled substances in accordance with the West Virginia Uniform Controlled Substances Act, were negligent in distributing controlled substances to pharmacies that serve individuals who abuse controlled substances, were unjustly enriched by such conduct, violated consumer credit and protection laws, created a public nuisance, and violated state antitrust laws in connection with the distribution of controlled substances. In addition to injunctive and other equitable relief, the attorney general is seeking monetary damages and the creation of a court-supervised fund, to be financed by the defendants in these actions, for a medical monitoring program focused on prescription drug abuse. Motions have been filed by all defendants to remove the cases to the United States District Court for the Southern District of West Virginia.

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## Part II. Other Information

### Item 1: Legal Proceedings

In addition to the proceedings described below, the legal proceedings described in Note 7 of the "Notes to Condensed Consolidated Financial Statements" are incorporated in this "Item 1-Legal Proceedings" by reference.

In May and June 2012, Herman Kleid and Henry Stanley, Jr., each purported shareholders, filed derivative actions on behalf of Cardinal Health, Inc. in the United States District Court for the Southern District of Ohio against the current and certain former members of our Board of Directors. A similar action was filed by Daniel Himmel, a purported shareholder, in the Common Pleas Court of Delaware County, Ohio and included certain of our officers as defendants. The complaints allege that the defendants breached their fiduciary duties in connection with the DEA's recent suspension of our Lakeland, Florida distribution center's registration to distribute controlled substances, and the suspension and reinstatement of such registrations at three of our facilities in 2007 and 2008. The Himmel action also makes claims based on corporate waste and unjust enrichment. The complaints seek, among other things, unspecified money damages against the defendants and an award of attorney's fees. In July and August 2012, the defendants filed motions to dismiss all three complaints. In October 2012, Herman Kleid voluntarily dismissed his complaint without prejudice and the court dismissed the Stanley action with prejudice. Separately, in September 2012, a purported shareholder made demand on our Board of Directors to take action against the current and certain former members of our Board of Directors to recover damages based on allegations similar to those set forth in the derivative actions above.

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### ITEM 3

## CHIEF ACCOUNTING OFFICER UPDATE

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ITEM 4  
ERNST & YOUNG, LLP

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ITEM 5  
CFO OVERVIEW

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TAX UPDATE

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## ITEM 7

### GLOBAL ASSURANCE SERVICES UPDATE

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### CHIEF INFORMATION OFFICER UPDATE

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## ITEM 9

### CHIEF LEGAL AND COMPLIANCE OFFICER UPDATE





**CARDINAL HEALTH CONFIDENTIAL**

To: Cardinal Health Audit Committee of the Board of Directors  
From: Craig S. Morford, Chief Legal and Compliance Officer  
Date: October 2012  
Subject: Annual Quality and Regulatory Report

This memorandum and the attached pre-read slides describe key challenges we and other healthcare companies face in the current regulatory environment and the actions we are taking to address those challenges. While the current regulatory environment has become more aggressive and less predictable, we accept this ever-changing reality and are taking actions to proactively manage our businesses accordingly. In our upcoming meeting, I will share observations and field any questions you may have about these or other regulatory matters.

**Overview of Current Regulatory Environment**

As Paul Keckley discussed during the August Board dinner, regulatory enforcement has become increasingly intense, especially under the current administration and particularly within the healthcare industry. Our businesses are impacted by a large number of federal, state and international agencies including DEA, FDA, HHS, NRC, OSHA, federal and state EPAs, Customs, State Boards of Pharmacy and State AGs. This Annual QRA Report will cover our management of overall quality/regulatory responsibilities, with particular focus on our two most impactful regulators from a QRA perspective – FDA and DEA.

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## DEA

The DEA continues to pursue the enforcement-oriented approach it began five years ago when it launched its initial "Distributor Initiative" to address the problem of controlled substance diversion through rogue Internet pharmacies that existed at that time. Prior to the sudden emergence of the rogue Internet pharmacy problem, DEA Diversion Investigators had approached the industry with a more regulatory-oriented mindset, addressing regulatory requirements in a way that avoided unnecessary adverse impacts to the legitimate supply chain. Although fines were occasionally assessed, they were generally proportionate to the nature of the infraction and registrants understood what was expected of them. Suspension of DEA Registrations was generally reserved for registrants engaged in criminal misconduct and grossly negligent registrants with little or no control programs.



In 2007, in response to the rapid growth of rogue Internet pharmacies and corresponding pressures from the media and Congress, the DEA began shifting significant criminal enforcement resources (special agents accustomed to prosecuting street criminals and illicit drug conspiracies) from the criminal side of the DEA to their regulatory side (the DEA Diversion Control Program). Unfortunately, former criminal agents often lack the regulatory experience to appreciate the medical implications aggressive enforcement actions can have on legitimate medical patients. Through its Distributor Initiative, the DEA sought to place greater responsibility for anti-diversion diligence on pharmaceutical distributors by focusing enforcement actions on distributors, including actions against ABC (2007), McKesson (2007) and Cardinal Health (2007).

It is the view of the DEA (and Congress, based on the findings of a recent GAO report) that this initiative was successful in significantly reducing the diversion of controlled substances through rogue Internet pharmacies. Unfortunately, while diversion through Internet pharmacies has significantly declined, demand for diverted substances has not and diverters quickly shifted from use of rogue Internet sites to the use of rogue pain clinics that both prescribed and dispensed controlled substances, and, more currently, to obtaining prescriptions from DEA registered physicians and then filling them at traditional chain and other retail pharmacies used by large numbers of legitimate patients. Third-party consultants and attorneys close to the DEA continue to advise us that DEA's focus on distributors will continue. The DEA also appears to be expanding their focus to include manufacturers and large chain pharmacies. DEA registration statistics show that while there are approximately 1.3 million practitioners (prescribing doctors) (92% of total DEA registrants), 67,000 retail pharmacies (5% of total registrants) and 16,000 hospitals and clinics (1% of total registrants), there are only approximately 500 manufacturers (.04% of total registrants) and 800 distributors (.06% of registrants). Of the 800 registered distributors, the vast majority of controlled substances are distributed through a very small number of distributors, the largest of which are McKesson, Cardinal Health, ABC and a few large, self-warehousing retailers. Similarly, of the 67,000 retail pharmacies, a large percentage are chain stores owned and operated by a small number of national companies (Walgreens, CVS, Rite Aid, etc.) and grocery/variety store companies (Walmart, Safeway, Kroger, etc.). In short, the DEA will continue to pressure distributors like Cardinal Health and large national retailers directly through the threat of enforcement actions and indirectly by placing pressure on upstream suppliers. During the past year, we have received first-time due diligence requests from manufacturers who have told us they are receiving increasing pressure from the DEA to perform diligence on their distributors. DEA has also brought enforcement actions against CVS, Walgreens and Cardinal Health (2012), as well as smaller distributors including Harvard Drug Group (6/10/11), Sunrise Wholesale (6/10/11) and KeySource Medical (6/11/11). In recent months, ABC disclosed their receipt of a criminal grand jury subpoena and a DEA administrative subpoena relating to a customer in New Jersey and ABC's anti-diversion program.

In addition to the continuing threat of enforcement actions, the DEA also continues to increase the frequency of its inspections of wholesaler and manufacturer facilities. DEA requested to increase its number of diversion investigators by 60 for FY11 and another additional 50 for FY12. As is the case with the FDA, this increase has resulted in the proliferation of less experienced regulatory inspectors. Additionally, criminal agents with little knowledge of the legitimate members of the supply chain are becoming increasingly involved in regulatory investigations. These trends are reinforcing the shift from a regulatory to an enforcement mindset.

We continue to assess our program in light of these changes and the regulatory action we experienced last year, and have implemented significant enhancements to our personnel and controls. We are also attempting to work more collaboratively with the agency. We have

reached out through several avenues to initiate greater dialogue and understanding with DEA headquarters and local offices. While some DEA personnel in field divisions have engaged in dialogue with us, DEA headquarters has been unresponsive to our communications. HDMA, our pharmaceutical distribution trade association, has expressed similar experience in its efforts to engage DEA in a meaningful way on behalf of all distributors. We are committed to improving the level of engagement and collaboration with DEA and are currently focusing our efforts on engaging with the DEA where these efforts are currently most productive – at the local field level.

I will be prepared to address any questions you may have regarding this information during our meeting next week.

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# 2012 Annual Quality and Regulatory (QRA) Report To The Audit Committee of the Board of Directors

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Craig Morford  
Chief Legal and Compliance Officer  
November 2, 2012





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# Shift in Regulatory Landscape





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- DEA: Aggressive posture continues, with particular focus on distributors and national chain pharmacies
  - CVS: (License revocation on FL stores; still in litigation phase)
  - Cardinal Health: Lakeland DC (License suspension; settlement reached; U.S. Attorneys in states of Maryland, Washington State, Tennessee and Florida exploring possibility of fines)
  - Walgreens: Jupiter DC license suspended; actions expected against 6-8 FL stores (we do not sell controlled substances to those stores)
  - ABC: ABC disclosed Criminal Grand Jury Investigation in SEC quarterly filing involving NJ Pharmacy and ABC's anti-diversion program



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# FY12 and FY13 YTD Pharmaceutical Segment Regulatory Inspection Performance

Business	Agency	No. of Inspections	Outcome	Status
Pharmaceutical Distribution	DEA	10	2 Observations. Observations related to documentation. 0 SOM Observations.	
NPS and Pharmacy Solutions			Related - Not Responsive	
	BoP, DEA	19	7 Observations	
			Related - Not Responsive	
PharmPak, 3PL and SPS	DEA	3 DEA (1-SPD; 3PL)	0 Observations	
			Related - Not Responsive	
Kinray	FDA, State, DEA	2	0 Observations	
			Related - Not Responsive	

Legend:  Satisfactory  Improvement Needed  Unsatisfactory



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# DEA: Major Changes to Our Anti-diversion Program to Meet Evolving Challenges

## Before

- More focus on retail independent customers (considered higher risk)
- Significant reliance on Chain Customers internal systems to investigate unusual ordering patterns
- Focus on all controlled substances (equal focus on all drug families)
- Focus on suspicious customers – those most likely diverting
- Reliance on internal expertise (CAH Pharmacists) with periodic external gap assessments
- Limited interaction with upstream business partners and large downstream chain partners
- Single decision making process for most decisions (SOM Team)

## Enhancements

- Increased focus on major retail chain customers
- More comprehensive review of chain customers' ordering patterns (Data analysis + Site visits)
- More focus on highly diverted controlled substance drug families
- More focus on suspicious orders regardless of our assessment of customer
- Greater reliance on external as well as internal expertise (CAH Pharmacists + former DEA Anti-diversion Experts)
- Greater interaction with upstream and large downstream chain partners
- Escalated decision making process for high risk/critical decisions
- Additional checks and balances, including committee review of higher volume customers



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ONLY**DEA: Memorandum Of Agreement (MOA) Progress Update**

MOA Requirements	QRA Progress	Requirements Met?
<b>Site Visits</b> <ul style="list-style-type: none"> <li>Site visits in response to Suspicious Orders for FL Customers (starting Jun. 3)</li> <li>Additional inspectors for FL</li> <li>Site visits in response to suspicious orders nationwide (starting Sep. 11)</li> </ul>	<ul style="list-style-type: none"> <li>Identified 13 drug families most likely to be diverted</li> <li>Streamlined site visit templates</li> <li>Visited ~85 pharmacies in FL (May 14 – Sep. 7)</li> <li>Contracted third party investigators</li> <li>Added 2 full-time FL investigators (7 total nationwide)</li> <li>Established same enhanced procedures and policies nationwide on Sep. 1</li> </ul>	    
<b>Establish Purchase Alert Limits (Thresholds)</b> <ul style="list-style-type: none"> <li>Review and enhance QRA processes for threshold setting</li> <li>Institute 2-person approval for increasing thresholds for larger volume customers for specific drug families</li> </ul>	<ul style="list-style-type: none"> <li>Re-set thresholds for oxycodone and hydrocodone for ALL pharmacy customers</li> <li>On track to apply new threshold setting methodology by Nov. 1, 2012 to the 11 additional drug families most likely to be diverted</li> <li>Executed for large volume customers</li> <li>Developed and executing approval process for all pharmacy customers</li> </ul>	  
<b>Large Volume Review Team</b> <ul style="list-style-type: none"> <li>Create Large Volume Review Team (LV-TAC) to perform deeper assessments of stores ordering larger volumes of higher risk drugs</li> </ul>	<ul style="list-style-type: none"> <li>Formed multi-discipline team (SVP QRA, Regulatory Counsel, VP of Anti-diversion program, outside DEA advisor)</li> <li>Conduct weekly/bi-weekly LV-TAC review meetings</li> <li>Reviewed ~460 stores (~190 independent and ~270 chain)*</li> </ul>	
<b>Suspicious Orders</b> <ul style="list-style-type: none"> <li>Report all suspicious orders to DEA whether we believe the customers are good or bad</li> </ul>	<ul style="list-style-type: none"> <li>Reported thousands of Suspicious Orders (SO) for 559 unique customers (101 in FL) for SOs nationwide*</li> <li>On track to execute accrual changes on Nov. 1, 2012</li> <li>Developed DEA metrics-driven framework for customer profiling</li> </ul>	
<b>Due Diligence</b> <ul style="list-style-type: none"> <li>Enhance customer due diligence (including chains)</li> </ul>	<ul style="list-style-type: none"> <li>Developed Sales Site Visit process</li> <li>QRA and Sales visited ~725* and ~750** customers, respectively (1,475 customers total)</li> <li>Terminated 126 (17 in FL) customers nationwide*</li> </ul>	

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# DEA: Relevant Cardinal Health Program Metrics

Category	FY10	FY11	FY12	2011 / 2012 Variance
Number of pharmacy site inspections by CAH	325	498	1,475	+414 (+83%)
Number of suspicious orders reported to the DEA	30	47	3,020*	+2,973 (+6,326%)
Number of customers blocked by QRA from purchasing controlled substances	60	36	218	+182 (+506%)
Number of prospective customers blocked by QRA from purchasing controlled substances	N/A*	18	27	+9 (+50%)

\* Prior to 2012, Cardinal Health followed the industry practice of focusing reports on orders by suspicious customers – those determined to be of interest to the DEA as potential diverters. Cardinal Health now reports all suspicious orders.

164 of 243

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# DEA: Anti-diversion Educational Tools/Programs for Customers

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- Increased focus on educating customer pharmacists on detecting potential diversion and understanding their corresponding responsibility required under the regulations to ensure that prescriptions are filled for a legitimate medical purpose.
- Provided educational materials to pharmacy customers (both community and chain)
- Provided multiple live Pharmacy Continuing Education courses to retail independent pharmacy customers at our Annual National Retail Business Conference (RBC) sales meeting (July 2012)
- Working closely with customers to engage with them when potential issues are identified



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# DEA: Continuing Areas of Focus Going Forward

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- High volume customers – focus on volume regardless of pharmacy's patient base or the prescriptions' seeming legitimacy
- Large chain customers – can't rely on the controls of large, publicly traded chains; will also conduct our own due diligence
- Changing nature of diversion – drug abuse continually shifting
  - Today = Oxycodone; Tomorrow?
  - Today = Florida; Tomorrow?
- DEA's approach presents challenges unlike other regulators:
  - Enforcement mindset leads to:
    - Less engagement with industry
    - Limited guidance or notice
  - In response, we are engaging with former DEA attorneys and consultants, as well as attempting to obtain informal guidance from local offices

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**CARDINAL HEALTH CONFIDENTIAL**

To: Cardinal Health Audit Committee of the Board of Directors

From: Craig Morford

Date: October 31, 2012

Subject: Quarterly Update – Q1 FY13  
Ethics and Compliance Program  
Enterprise Risk Management

**Q1 FY13 Ethics and Compliance Program update**

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Audit Committee of the Board of Directors  
Quarterly Update – Q1 FY13  
October 31, 2012  
Page 4 of 5

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- Enterprise Risk Management:

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Audit Committee of the Board of Directors  
Quarterly Update – Q1 FY13  
October 31, 2012  
Page 5 of 5

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Appendix B - Board of Directors Enterprise Risk List

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# Board of Directors November 2012

## Enterprise Risk List

### Appendix B

Risk Name	Risk Description	Risk Owner	Mitigation	Oversight	Date First Addressed with Board	Date Last Addressed with Board	Status Update	Strategy Alignment
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DEA Regulatory Action	Risk of DEA regulatory action and/or disruption at Cardinal Health facilities.	Craig Morford/ Mike Kaufmann	<ul style="list-style-type: none"> <li>Suspicious order monitoring program staffed by experienced pharmacists</li> <li>Know your Customer program</li> <li>Advanced analytics to drive focused customer visits</li> <li>Focused approach re: higher risk areas (e.g., Florida)</li> <li>Business continuity – back up DEA and state licensure</li> <li>DEA meetings – attend and monitor</li> </ul>	Quality Council	Nov-10	Nov-12 (Audit Committee)	Corporate Audit verified the mitigation process presented to the Board and confirmed that based on the review procedures performed the mitigation plans have been implemented as communicated to the Board of Directors.	Operational Generics Ambulatory Care

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# Board of Directors November 2012

## Enterprise Risk List

### Appendix B

Risk Name	Risk Description	Risk Owner	Mitigation	Oversight	Date First Addressed with Board	Date Last Addressed with Board	Status- Update	Strategy Alignment
DEA Regulatory Action (cont'd)							Update: On February 3, 2012, the DEA issued an immediate suspension / show cause order against the controlled substances registration for the Cardinal Health distribution center in Lakeland, Florida. Cardinal Health is pursuing legal avenues to challenge the action and has implemented business continuity plans.	
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ITEM 10  
GENERAL COUNSEL UPDATE



**CARDINAL HEALTH CONFIDENTIAL**

October 26, 2012

Cardinal Health Audit Committee  
Cardinal Health, Inc.  
7000 Cardinal Place  
Dublin, Ohio 43017

Dear Audit Committee Members:

We are pleased to provide you with this report of lawsuits and claims.

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Please do not hesitate to call me if you have any questions.

Very truly yours,

A handwritten signature in black ink that reads "Steve". The signature is written in a cursive, slightly stylized font.

Stephen T. Falk  
EVP, General Counsel & Secretary

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**2(a). Lakeland, Florida Distribution Center DEA Investigation  
(Pharmaceutical Segment)**

- **Brief Description:** U.S. Drug Enforcement Agency ("DEA") investigation of controlled substance procedures and processes at the Company's Lakeland distribution center with respect to Florida pharmacies, including CVS chain stores.

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- **Matter History:** In October 2011, DEA issued a Warrant for Inspection to our Lakeland distribution facility and collected records relating to the distribution of controlled substances from the facility, including information on particular customers that had purchased the largest amounts of oxycodone from August 2010 through May 2011. In November, DEA served an administrative subpoena requesting additional records. In connection with this matter, Cardinal Health ceased distribution of controlled substances to some pharmacy customers.

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On February 3, 2012, DEA served the Company's Lakeland facility with an immediate suspension order ("ISO") of the facility's DEA registration and an Order to Show Cause why the facility's DEA registration should not be revoked. The Company was granted a TRO to the ISO by the U.S. District Court for the District of Columbia, which was then dissolved on February 29 when the Court denied the Company's preliminary injunction motion. On March 2, the U.S. Court of Appeals for the District of Columbia Circuit granted an administrative stay to the ISO, which was dissolved on March 16 when the appellate court denied the Company's motion for a stay for the duration of the appeal.

On May 14, 2012, Cardinal Health and the DEA reached a settlement in this matter. The terms of the settlement include an agreed-upon two-year suspension of the Lakeland facility's controlled substance registration, a release from DEA administrative claims (e.g. license suspensions) for all Company distribution facilities for prior acts, and agreed-upon enhancements to our anti-diversion system. The settlement does not include a monetary component, although the DEA expressly reserved the right to seek potential civil fines through referrals to U.S. Attorneys' offices.

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**3(a). Shareholder Derivative Litigation (Corporate)**

- **Brief Description:** Shareholder derivative lawsuits alleging breach of fiduciary duties in connection with DEA proceedings.

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- Matter History: In May and June 2012, three shareholder derivative lawsuits were filed in Ohio state and federal courts against certain of the Company's current and former directors and officers ("Defendants") in connection with the DEA's proceedings against Cardinal Health in 2007-2008 and 2011-2012. In all three cases, plaintiffs allege that Defendants breached their fiduciary duties by failing to adequately monitor the Company's efforts, to cause the Company to implement an adequate system of controls, and to prevent diversion of controlled substances, thereby causing the Company to incur expenses and other harm in connection with the defense and resolution of the two DEA proceedings. Motions to dismiss have been filed in all three cases.

### **3(b). DEA/AUSA Civil Penalty Referrals (f/k/a Baltimore MSI Subpoenas) (Pharmaceutical Segment)**

- Brief Description: Inquiries by AUSA offices regarding controlled substance distributions following Lakeland DEA investigation and settlement.

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- Matter History: On July 20, 2010, Cardinal Health received a subpoena from DEA requesting certain records related to the distribution of controlled substances to four Medicine Shoppe franchisees in the Baltimore area. On March 30, 2012, the Company received two more subpoenas requesting information relating to two prescribing physicians and five stores (three retail independent stores and two CVS stores) to which Cardinal Health distributed controlled substances. The DEA also asked to interview employees from the Company's compliance and sales groups. Based on statements made by the DEA during the settlement of the Lakeland DEA investigation, and discussions with the Assistant U.S. Attorney managing the case, we now understand that the Baltimore AUSA will be seeking a financial penalty for the alleged failures to report suspicious orders. We met with the DEA and the Baltimore AUSA on July 17, 2012, during which we learned of the activity of three other U.S. Attorney's offices along similar lines.

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#### **4. EXISTING MATTERS WITHOUT SIGNIFICANT DEVELOPMENTS**

**4(a). State of West Virginia vs. Cardinal Health, Inc. (Pharmaceutical Segment):** Suit by West Virginia Attorney General relating to controlled substance distributions in the State of West Virginia.

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ITEM 11  
AUDIT COMMITTEE MATTERS

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ITEM 12  
AUDIT COMMITTEE SESSIONS ALONE

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**CARDINAL HEALTH CONFIDENTIAL**

To: The Audit Committee of the Board of Directors  
From: Craig Morford, Chief Legal and Compliance Officer  
Date: October 26, 2012  
Subject: Reports involving VPs and above and other significant cases

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